UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte FATIH M. UCKUN

Appeal No. 2005-0904
Application No. 09/272,821

HEARD: JUNE 23, 2005

Before ELLIS, SCHEINER and ADAMS, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 23-44, the only claims remaining in the application. Claims 23-44 are reproduced in Appendix I accompanying appellant's Brief on Appeal of February 27, 2004.

The reference relied on by the examiner is:

Lind et al. (Lind)	WO 93/03022	Feb. 18, 1993

The claims stand rejected as follows:

I. Claims 23, 25, 26, 29-31, 34-36, 39, 41 and 42 under the first paragraph of 35 U.S.C. § 112 (enablement).

II. Claims 23, 25, 26, 29-31, 34-36, 39, 41 and 42 under the second paragraph of 35 U.S.C. § 112 (indefiniteness).

III. Claims 23-44 under 35 U.S.C. § 103 as unpatentable over Lind.

We reverse these rejections.

DISCUSSION

Enablement

In its broadest aspect, the present invention is directed to inhibiting replication of "an HIV strain that is resistant to a chemotherapeutic agent," comprising contacting the resistant virus with N-[2-(2-fluorophenethyl)]-N'-[2-(5-bromopyridyl)]-thiourea (termed DDE240 in appellant's specification) or N-[2-(2,5-dimethoxyphenylethyl)]-N'-[2-(5-bromopyridyl)]-thiourea (termed DDE236 in appellant's specification), in an amount effective to inhibit replication of the virus (e.g., claim 23).

Claims 23, 25, 26, 29-31, 34-36, 39, 41 and 42 stand rejected under the first paragraph of 35 U.S.C. § 112, as unenabled by the specification. According to the examiner, "[a]pplicant fails to set forth the criteria that allow[ ] the skilled artisan to identify those HIV strains 'resistant to a chemotherapeutic agent'" (Answer, page 4), "absent undue experimentation" (id.).

While "enablement requires that the specification teach those in the art to make and use the invention without 'undue experimentation,' [the fact] [t]hat some experimentation may be required is not fatal; the issue is whether the amount of experimentation is 'undue.'" In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991) (citation omitted, emphasis in original). "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).[1]

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[1] Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman [230 USPQ 546, 547 (BdPatAppInt 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples,

"[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971) (emphasis in original). "[I]t is incumbent upon the Patent Office . . . to explain why it doubts the truth and accuracy of any statement in the supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." Id. at 224, 169 USPQ at 370. Thus, "the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification." In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

Accordingly, the dispositive issue here is not whether appellant has established that the disclosure is broadly enabling for the scope of the claims, rather, the issue is whether the PTO has met its "initial burden of setting forth a reasonable explanation as to why" it is not. Keeping this in mind, we consider the specific reasons provided by the examiner in support of his position.

(continued)

(4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims (footnote omitted).

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The examiner argues that the specification "fail[s] to provide sufficient working examples" because "only a limited number of HIV strains 'resistant to a chemotherapeutic agent' [ ] are set forth," and the examples "are neither exhaustive, nor [do they] define the class of [chemotherapeutic agent] required." Answer, page 4.

In our view, the examiner has not established a reasonable basis to question the adequacy of the disclosure provided for the claimed invention. The specification describes a number of drug-resistant strains of HIV in Tables 1 and 2, and also teaches that drug resistant strains of HIV can be identified by treating infected cells with non-nucleoside reverse transcriptase inhibitors like Nevirapine, Delavirdine and Efavirenz. Specification, pages 8 and 12. Moreover, other classes of anti-HIV drugs are mentioned in the specification, for example, nucleoside analogs (such as AZT), and protease inhibitors (such as Nelfinavir). The examiner has not explained why it would have been anything other than straightforward for one skilled in the art to test HIV-infected cells for resistance to any known anti–HIV drug.

In any case, we know of no authority that would limit appellant to the specification's working examples, simply as a matter of course, without evidence or reasoning of the kind discussed above on the part of the examiner. Instead of evidence or reasoning, however, we find a conclusory assertion that "[t]he pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity" (Answer, page 4).

Without belaboring the record, we will simply say that the examiner would improperly shift the burden of going forward to appellant, without having first discharged his own burden by backing up his assertions with acceptable evidence or a

fact based analysis in keeping with that described in Wands. Accordingly, the rejection of claims 23, 25, 26, 29-31, 34-36, 39, 41 and 42 under the first paragraph of 35 U.S.C. § 112 is reversed.

Indefiniteness

Claims 23, 25, 26, 29-31, 34-36, 39, 41 and 42 stand rejected under the second paragraph of 35 U.S.C. § 112. According to the examiner, "[c]riteria defining HIV strains 'resistant to a chemotherapeutic agent' are not set forth in the specification, thereby failing to provide information defining the instant invention['s] metes and bounds." Answer, page 5.

Nevertheless, the test for definiteness is simply whether one skilled in the art would understand the language of the claims when the claims are read in light of the specification. See Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). As discussed above, the specification identifies several drug-resistant strains of HIV, and also explains that resistant strains can be identified by testing infected cells with various known anti-retroviral agents. Having reviewed the claims in light of the specification, we find them to be complete and understandable, and we are not persuaded that one skilled in the art would have any difficulty in interpreting their metes and bounds.

Obviousness

Claims 23-44 stand rejected under 35 U.S.C. § 103 as unpatentable over Lind. Lind teaches that many known anti-HIV compounds "suffer from toxicity problems, lack of bioavailability . . . , viral resistance, or combinations thereof" (Lind, page 3), and describes "[thiourea] compounds and pharmaceutically acceptable salts thereof to

inhibit and or treat HIV and AIDS" (id.). According to appellant, Lind's generic formulas "cover[ ] millions of compounds[;]" and the reference "recite[s] a dictionary list of thousands of compounds[;]" about 450 of which were actually made and tested for the ability to inhibit the activity of HIV reverse transcriptase (Brief, note 7). While DDE240 is listed on page 106 of the 500+ page reference, and DDE236 is listed on page 108, appellant notes they "were not made nor tested for . . . [anti-] HIV activity" (id., note 8).

The examiner does not dispute appellant's characterization of Lind, but argues that "the claimed compounds [are] old . . . [and] taught as useful for treating viral infections generally, [and HIV] specifically" (Answer, page 6); Lind "set[s] forth the issue of HIV resistance to conventional antiviral agents" (id.); and "[p]ossessing this teaching, the skilled artisan would see the instant compounds, taught as anti-HIV . . . as useful for treating resistant HIV strains" (id.).

The examiner's position appears to be, quite simply, that it would have been obvious per se to use each and every species described by Lind to inhibit HIV. While the proposition that "there is nothing unobvious in choosing 'some' among 'many' indiscriminately" has a certain appeal, In re Lemin, 332 F.2d 839, 841, 141 USPQ 814, 815 (CCPA 1964), our reviewing court has repeatedly indicated, in these or similar words, that "reliance on per se rules of obviousness is legally incorrect and . . . is simply inconsistent with section 103." In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995); see also In re Brouwer, 77 F.3d 422, 425, 37 USPQ2d 1663, 1666 (Fed. Cir. 1996).

Several considerations are relevant to the determination of whether a species would have been obvious over a description of a genus encompassing the species. Merely by way of example, the size of a genus relative to a claimed species may have a

bearing on the determination. A very broad genus, without more, may weigh against a determination that a species is obvious over the genus; even a relatively small genus does not create an automatic presumption of obviousness - there must still be some reason, stemming from the prior art, to select the claimed species, see, e.g., In re Baird, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994); In re Jones, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943-44 (Fed. Cir. 1992), (although, a very small genus may actually anticipate each member of the genus, see In re Petering, 301 F.2d 676, 682, 133 USPQ 275, 280 (CCPA 1962)).

A related consideration is whether the prior art highlights any "typical," "preferred," or "optimum" species within the genus. Highlighted species different from those claimed may weigh against a determination of obviousness. "A disclosure of millions of compounds does not render obvious a claim to three compounds, particularly when that disclosure indicates a preference leading away from the claimed compounds." In re Baird, 16 F.3d at 382, 29 USPQ2d at 1552. In re Baird, 16 F.3d at 382, 29 USPQ2d at 1552. On the other hand, typical, preferred, or optimum species structurally similar to those claimed may be evidence supporting a determination of obviousness. In re Dillon, 919 F.2d 688, 696, 16 USPQ2d 1897, 1904 (Fed. Cir. 1990).

Yet another consideration is the disclosure of any useful properties of the prior art compounds. "[T]he lack of any disclosure of useful properties may indicate a lack of motivation to make related compounds," or, more to the point here, a lack of motivation to select a species from a disclosed genus, weighing against a determination of obviousness. See In re Dillon, 919 F.2d at 698, 16 USPQ2d at 1906.

Appellant points out, among other things, that one would have to "go through the millions of compounds disclosed by Lind [ ] to reach one of the two compounds recited

in the present claims" (Brief, pages 11-12, footnotes omitted), that Lind "do[es] not disclose any activity data for the two [claimed] compounds" and that "the most structurally similar compound tested has inferior activity against [ ] HIV"[2] (id., page 12). The examiner's rejection, on the other hand, addresses none of these factors. In our judgment, the examiner's rejections are improperly based on a per se rule of obviousness, rather than on any reason or suggestion in Lind to select the claimed species from the vast number of formulas described therein.

The initial burden of presenting a prima facie case of obviousness rests on the examiner. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). The rejection of claims 23-44 under 35 U.S.C. § 103 is reversed because the examiner has not established that inhibition of HIV (drug-resistant or not) with DDE240 or DDE236 would have been suggested by the prior art.

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[2] In response to appellant's arguments, the examiner points to the fifth compound in Lind's Table A2 as representing "the core structure of [the instant] compound[s]" (Answer, page 12). Appellant notes that "the data disclosed in Lind [ ] indicates that 1-Phenethyl-3-pyridin-2-yl-thiourea, the 'core' of the compounds recited in the present claims is considerably less effective than other compounds having different cores" (Brief, page 14). In addition, we note that the examiner also points to compound V of Lind's Claim 57, wherein R_d is halogen, as a positional isomer of the claimed compounds. We further note, however, that compound V is the subject of a negative proviso - it is specifically excluded from Lind's claim.

CONCLUSION

On consideration of the record, the rejections of the claims under the first and second paragraphs of 35 U.S.C. § 112, and under 35 U.S.C. § 103 are reversed.

REVERSED

Joan Ellis
Administrative Patent Judge

Toni R. Scheiner
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

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